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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,242	07/02/2003	Yvo Maria Franciscus Graus	05032-00031	3317

22910 7590 08/02/2006

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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,242	GRAUS ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-59* is/are pending in the application.

4a) Of the above claim(s) *49-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0703 & 0705*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Upon further review, the previous Election/Restriction requirement was deemed incomplete because claims 49 and 50 should not have been included in the Group I invention. Claims 49 and 50 constitute a new group (Group V) - drawn to a method of treating/preventing cancer (classified in class 424/725, for example), which is restrictable from the other inventive Groups (Groups I-IV) for the same reasoning set forth in the previous Office action.

During a telephone conversation with John Iwanicki on 29 June 2006 an election was made with traverse to prosecute the invention of Group I, now claims 24-48, for the same reasoning as discussed in the written reply filed 23 June 2006 which is set forth below.

Applicant's election with traverse of Group I (now claims 24-48) in the written reply filed on 23 June 2006 is acknowledged. The traversal is on the ground(s) that the subject matter of instant claims is interrelated to the extent that a search and examination of the subject matter would not be overburdensome, and further that Group III (claims 55-58) is drawn to a method of stimulating T-lymphocytes *in vivo* via administering the preparation of claim 24. This is not found persuasive for the reasons set forth in the previous Office action. It is reemphasized that the search for each of the inventive groups is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Please also note that if the product claims are ultimately found allowable, Applicants will be entitled to rejoinder to an appropriate (enabled) method of use claim (as recited in claim 55).

The requirement is still deemed proper and is therefore made **FINAL**.

In addition, Applicants' election of the following species in the reply filed 23 June 2006 is acknowledged - *Echinacea* species (species A), chlorogenic acid (species B), *Echinacea* species (species C), trace elements (species E), copper (species F), and viruses (species G).

Claims 24-50 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly recited chlorogenic acid (or functional analog) to zinc ratio ranges instantly claimed - i.e., "0.0025 to 500" (claim 24 - which apparently was first recited in newly added claim 29 within the preliminary amendment filed 02 July 2003), "0.0025 to 2.5" (claim 30), "0.5 to 2.5" (claim 31), and "0.5 to 500" (claim 32) are deemed new matter as no support could be found within the instant specification for such ratio ranges.

Applicant is required to cancel the new matter, or to particularly point to support for the recited ratio ranges within the instant specification, in the reply to this Office Action.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, first paragraph for the reasons set forth above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-27 and 41-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25, 26, 41 and 43 are rendered vague and indefinite by the phrase "preparation according to claim ... comprising" because it is unclear if this recitation is attempting to define an alternative embodiment to the limitations set forth in the claims from which these claims depend. It is suggested that the term "comprising" be expanded to recite --further comprising-- to clarify this ambiguity.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,632,459. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to a preparation for stimulating or enhancing an immune system comprising chlorogenic acid or functional analog thereof and zinc, as well as the other ingredients recited in the instant claims and in the claims of '459. In addition, please note that the instant claims encompass or are encompassed by the claimed invention of '459.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24, 28, 30, 31, 32, 37-43, 45, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Coudray et al. (Br. J. Nutrition, 1998) .

A preparation comprising chlorogenic acid and zinc (within expansive ratio ranges) is claimed. Dependent claims include the preparation further comprising a component such as polysaccharides, trace elements, and/or vitamins.

Coudray et al. teach a dietary food (meal) preparation comprising chlorogenic acid to which zinc is also added. The reference ratio range of chlorogenic acid to zinc is within the expansive ratio ranges instantly claimed. The reference meal preparation further comprises polysaccharides (in the form of starch, cellulose, etc), other trace elements such as copper, and vitamins. This reference further teaches that the polyphenol meal preparation (containing the polyphenol chlorogenic acid) is prepared as a semi-liquid food (thus, reads upon a solution, liquid, gel, and/or suspension). See, e.g., page 576 under the headings *Animals and diet* and *Polyphenol study: acute effect of polyphenol ingestion on zinc and copper absorption.*

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 24, 28, 30, 31, 32, 37-43, 45, 47, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Chekalinskaya et al. (Rastitel'nye Resursy, 1983 - CAPLUS Abstract).

Chekalinskaya et al. teach that *Oxycoccus palustris* fruit (reads upon a food product) naturally comprise chlorogenic acid and zinc (Zn) that fall within the expansive ratio ranges instantly claimed. Accordingly, the reference fruit product reads upon the instantly claimed preparation. This reference further discloses that *Oxycoccus palustris* fruit naturally comprise other trace element such as manganese (see CAPLUS Abstract). Please note that such a fruit product would inherently comprise naturally-occurring polysaccharides therein.

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 24, 28, 30, 31, 32, and 37-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Ameziane et al. (Bull. Soc. Chim. Fr. (1996).

Ameziane et al. teach a preparation comprising chlorogenic acid (as a ligand) and zinc (Zn) that fall within the expansive ratio ranges instantly claimed (see, e.g., pages 239-240 - first paragraph under the heading *Chlorogenic acid-metal cation interactions*, and Figure 2).

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 24, 28, 30, 31, 32, 37-45, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coudray et al. (Br. J. Nutrition, 1998).

The Coudray et al. reference is relied upon for the reasons set forth above. Although not expressly taught, it would have been obvious to include vitamin A and/or vitamin E within the vitamin mixture disclosed by Coudray et al. since both of these commonly-employed vitamins are notoriously well known in the art to be beneficially healthful when incorporated within a balanced vitamin-fortified meal/food. If not expressly taught, the adjustment of particular conventional working conditions (e.g., preparing such a meal formulation within a food bar or agglomerate) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the reference, especially in the absence of evidence to the contrary.

Claims 24, 28, 30, 31, 32, 34, 35, 37-40, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (US 5,780,060).

Levy et al. beneficially teach pharmaceutical compositions in the form of orally-administered microcapsules (which also reasonably read upon a food product) whereby the microcapsule comprises or may comprise chlorogenic acid and zinc oxide therein (see, e.g., col 4, lines 1-19 and col 5, lines 41-57).

It would have been obvious to one of ordinary skill at the time the claimed invention was made to provide an oral tablet or capsule formulation comprising chlorogenic acid and a zinc compound/salt such as zinc stearate or zinc oxide based upon the beneficial teachings provided by the cited reference, as discussed above. The adjustment of particular conventional working conditions (e.g., determining an appropriate amount of chlorogenic acid and zinc oxide therein, and/or substituting an equivalent zinc salt form thereof) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the cited reference, especially in the absence of evidence to the contrary.

Claims 24-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu (US 6,083,921), Squires (WO 98/11778), Carenzi et al. (US 5,080,906), and the admitted state of the art.

Xu beneficially teaches an anti-viral pharmaceutical composition comprising chlorogenic acid (including chlorogenic acid obtained from a plant) as an active immunomodulating agent therein. Xu further beneficially teaches such pharmaceutical compositions may be in the form of a tablet (which reasonably reads upon a food product) and that the tablet can include zinc stearate as a conventional ingredient therein (see entire document including abstract, col 3, lines 39-51, col 5, line 48-col 6, line 59; col 10, line 54 - col 11, line 15).

Squires beneficially teaches a pharmaceutical composition useful for treating viral infections including HIV comprising a functional analog of chlorogenic acid (such as 1,5-o-dicaffeoylquinic acid - among others - which is encompassed by 1,5-dicaffeoylquinic acid as well as by the chemical structure shown in claim 38). The reference also discloses that the composition comprises or my comprise polysaccharides, arabinogalactan, vitamin E (tocopherol), vitamin A (ascorbic acid), minerals, and plant extracts such as some of those instantly claimed (e.g., *Echinacea, Calendula* extracts)- see, e.g., pages 4-8, 10, 11, 14-16, and claims.

Carenzi et al. disclose that it is well known in the art to use N-acetyl cysteine in human therapy to beneficially stimulate immune systems debilitated by viral infections, including those debilitated by HIV (see, e.g., col 1, lines 11-21).

In addition, as readily admitted by Applicants (and/or as well recognized in the art), many of the instantly claimed additional ingredients are well known in the art to act as anti-viral and/or immunostimulant agents (see, e.g., pages 10-13 of the instant specification).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit (e.g., as antiviral agents) since each is well known in the art for the same purpose and for the following reasons. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Sussman, 1943 C.D. 518; In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. The adjustment of particular conventional working conditions (e.g., substituting zinc stearate for another equivalent zinc compound/zinc salt and/or determining an appropriate amount ratio of chlorogenic acid/analog to zinc compound/salt therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references (as well as the admitted state of the art), it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

With respect to of the USC 102 and 103 rejections above, please note that each of the chlorogenic acid-zinc containing products taught or reasonably suggested by the cited references would intrinsically be capable of providing the intended functional effect(s) instantly claimed. In addition, the source from which the chlorogenic acid is obtained is not deemed to lend patentable distinction to the instantly claimed chlorogenic acid since chlorogenic acid is a defined chemical structure which would not vary regardless of from which source it is obtained (e.g., whether it is obtained from a particular plant source or is synthetically made, it still is the same chemical compound with the same chemical structure and, thus, would not be distinguishable based upon such a source limitation).

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher R. Tate
Primary Examiner
Art Unit 1655